

Memorandum

DATE: May 31, 2001

TO: Sandra Titus

FROM: Matt Speakman

RE: FDA public advisory committee meeting

CC: [Patty Engel, Orphan Medical]

Sandra:

As a narcolepsy patient successfully treated with XYREM, the drug which is to be discussed at the upcoming public advisory meeting, I would like to be allotted no more than 5 minutes to make the following statement.

Six years ago, as I entered my senior year of high school, my grades were slipping, my attitude was negative (to say the least), and my efforts to receive an appointment to the United States Naval Academy were useless.

I had recently been diagnosed with the condition called narcolepsy, a sleep disorder that effects the brain and causes severe daytime sleepiness and cataplexy, a sudden and nearly complete loss of muscular control.

I quickly learned that narcolepsy is a very rare disorder, about which little is known, and for which there are few effective treatments. I spent my remaining year of high school sleeping through class (averaging about 16 to 18 hours of sleep a day), angering my teachers (who suspected drug abuse), and in a generally foul disposition which affected my friendships, relationships, family life, and academic efforts.

I struggled to make it through my first year of college at the University of Kentucky, finding it difficult to awake for classes on time, and to meet friends who would understand the strange behavior patterns that result from "passing out" every few hours.

Determined to find some way to better my condition, my mother searched to find a specialist who dealt with cases such as mine. She found such a specialist in nearby Cincinnati who promised a "wonder drug" and that my life would undoubtedly change for the better.

I was skeptical. I had dealt emotionally with my disorder and had come to a realization that I would live this way for the rest of my life. I had little hope for success in the future, as I wondered what kind of employer would hire such a person.

After my first week of trial medication of GHB, which is now called XYREM, I can not fully explain to you the changes that occurred. Instead of desperately trying to stay awake during the day, I was functioning at nearly 100%. Instead of fighting restlessly at night to maintain a constant sleep, I rested deeply and soundly. The cataplectic attacks (the real monster of narcolepsy) ceased almost completely. Over the past 4 years of using XYREM I have had 4 cataplectic episodes (and only because I failed to take the medication while pulling all-night study sessions). This number is reduced from the 6 to 8 cataplectic episodes a WEEK that I experienced before treatment.

Two weeks ago, I graduated from West Virginia University (cum laude) with a Fine Art degree in graphic design. This week I will send resume's and portfolio all over the country. My ambition and energy (characteristics for which I have always been known) are restored along with my confidence of success in the future. I have built strong friendships and relationships. I have established professional contacts and experience within the field of graphic design.

THE MESSAGE: None of this would be possible without effective treatment for my sleep disorder. My experience with XYREM has been without side effects. YES, without side effects (unless you consider happiness, hope, and confidence to be side effects). I understand and agree with concerns regarding the abuse and misuse of GHB...or any drug for that matter. That is why I ask for a solution to this matter to be resolved as quickly as possible. There are thousands of other narcoleptics who need this treatment, and there are thousands of victims from abuse and misuse of this drug. Please approve the medication for those who need it, regulate it appropriately, and penalize those who abuse it.

Thank you.

-Matt Speakman

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